REMARKS

Claims 1-13, 15-18, 20-30, 34, 37-42, 44, 45 and 48-60 are pending in the present application. Claims 1 and 59 are in independent form. Claims 59 and 60 are newly-added. In view of the above amendments and the following remarks, favorable reconsideration and allowance of the present application is respectfully requested.

I. CLAIM AMENDMENTS

By the present Amendment, claims 59 and 60 are newly-added. The subject matter recited in claims 59 and 60 is supported, at least, by original claim 1 and paragraph [0067] of the published Specification, U.S. Publication No. 2007/0178446 A1.

Thus, Applicants submit that the amendments do not introduce new matter.

II. CLAIM OBJECTION

Claim 43 stands objected to for being in improper dependent form by allegedly failing to further limit the subject matter of a previous claim. In particular, the rejection states that claim 43 contains the same limitations as claim 41.

By the present Amendment, claim 43 has been cancelled. Thus, the rejection has been rendered moot.

III. CITED ART REJECTION

(A) Claims 1-13, 15-18, 20-30, 34, 37-45 and 45-58 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Tuompo et al. (hereinafter "Tuompo"), U.S. Patent No. 5,714,343 in view of Koumura et al. (hereinafter "Koumura"), U.S. Patent No. 4,591,554. Applicants respectfully traverse the rejection.

i. INDEPENDENT CLAIM 1

Independent claim 1 is directed to a method of detecting contaminants in a medium suspected of containing such contaminants including (*inter alia*) "d) evacuating the liquid vehicle from the influent side of the filter by forcing the liquid vehicle through to the effluent side of the filter" and "e) performing a quantitative or qualitative detection of the detectable moiety in the liquid vehicle evacuated in step d and correlating the detection of the moiety to the amount or presence of contaminants in the sample." Applicants submit that the combination of Tuompo and Koumara fails to explicitly teach, or otherwise suggest, the above features recited in independent claim 1.

In particular, acknowledging the deficiencies of Tuompo with respect to steps d) and e) as recited in independent claim 1, the rejection states that "[i]t would have been obvious to one of ordinary skill in the art at the time of the invention to evacuate (elute) the colored enzymatic reaction product by applying either an elevated pressure on the influent side of the filter or applying a lowered pressure on the effluent side of the filter because one of ordinary skill in the art would have recognized this as an automation of the

gravity filtration process taught by Tuompo et al. when using the MTT substrate and the automation of a previously manual activity is *prima facie* obvious (See MPEP, *In re Venner*)." Action, p. 8.

However, Applicants submit that nothing in Tuompo implies that the MTT should be detected in the test solution on the effluent side of the filter. That is, detection could be performed by analysis of the filter or the liquid on the influent side of the filter. Apart from this, Tuompo states that "[i]ndeed, NBT is a preferred chromogenic reagent for use in the invention..." Tuompo, col. 3, ll. 9-13. Also, "NBT and MTT are equally rapid from the point of view of color formation, but the advantage of NBT in comparison with MTT is that the color can be deposited on a restricted area of the filter because it precipitates at the point where the dehydrogenases are situated around the bacteria." Tuompo, col. 3, ll. 14-18.

Furthermore, in the examples provided in Tuompo, the cells are counted directly on the filter, and small amounts of the test solution including the chromogenic agent are used. Tuompo does not suggest the use of larger volumes of test solution which would be needed in order to perform detection on any test solution that passes through the filter.

Koumura, which is directed to a method for detecting microorganisms, does not use a filter.

Furthermore, if using the larger volumes of test reagent as taught in Koumura, Koumura teaches that centrifugation is used to separate contaminants from the test reagent. If using the smaller volumes as taught by Tuompo, one would inspect the filter directly. Thus, the combination of Tuompo and Koumura does not lead one to perform steps d) and e) as

recited in claim 1. Therefore, Koumura fails to remedy the above-noted deficiencies of Tuompo with respect to independent claim 1.

Applicants respectfully remind the Examiner that, in order to establish a *prima facie* case of obviousness predicated on a combination of documents, the combination must teach, or suggest, all of the claim limitations, cf. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Or, if the documents are missing claimed features, there must be some apparent reason either in the documents or the general knowledge in the art by which to modify the documents to include the missing subject matter in the fashion claimed, cf. Id. and KSR Int'l, Co. v. Teleflex Inc., 550 U.S. 398, 418, 82 USPQ2d 1385, 1396 (2007) (obviousness includes determining whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue).

Further, MPEP §2143 states that "...[t]he key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious..." which should be made explicit and must be anchored by a rational underpinning, as directed by KSR Int'I Co. v. Teleflex Inc.

Neither Tuompo nor Koumura teaches the combined steps of passing the liquid medium through the filter and subsequently determining a "detectable moiety" on the effluent side of the filter. Furthermore, neither the references nor the common general knowledge provides for "an apparent reason" to determine the detectable moiety on the effluent side of the filter:

For at least these reasons, Tuompo in view of Koumura fails to explicitly teach, or otherwise suggest, a method of detecting contaminants in

a medium suspected of containing such contaminants including (*inter alia*) "d) evacuating the liquid vehicle from the influent side of the filter by forcing the liquid vehicle through to the effluent side of the filter" and "e) performing a quantitative or qualitative detection of the detectable moiety in the liquid vehicle evacuated in step d and correlating the detection of the moiety to the amount or presence of contaminants in the sample" as recited in independent claim 1.

Accordingly, Applicants respectfully request that the Examiner reconsider and withdraw the rejection to independent claim 1, and claims 2-13, 15-18, 20-30, 34, 37-42 and 44-58 at least by virtue of their dependency on independent claim 1.

IV. NEWLY-ADDED INDEPENDENT CLAIM 59

Newly-added independent claim 59 is directed to a method of detecting contaminants in a medium suspected of containing such contaminants including (*inter alia*) "allowing the substrate to interact with the contaminants on the influent side of the filter in the filter device for a period of time between 5-minutes to 24-hours, which is sufficient to allow the detectable moiety to be detected in the liquid vehicle." Applicants submit that independent claim 59 is also patentable over the combination of Tuompo and Koumura.

In particular, the rejection states that Tuompo et al. teaches a method for the detection of viable microorganisms including "...allowing the chromogenic substrate to interact with the microorganisms (bacteria) for a period of time wherein the interaction is not terminated..." Action, p. 5.

However, Tuompo teaches that "[a]fter filtration to separate microorganisms in the sample from any free reducing compounds present in the sample, a test solution containing a chromogenic reagent is added and drawn through the filter." Tuompo, col. 2, ll. 53-56. Thus, there is no teaching in Tuompo that the test solution should remain on the influent side of the filter to allow a reaction to take place before passing the test solution to the effluent side of the filter. That is, Tuompo describes a method, where bacteria are detected on the filter by means of a precipitated chromogenic agent. In Tuompo, it is merely important that the chromogenic agent is brought into contact with the filter surface, where it can precipitate. However, the time interval where the chromogenic agent is present on the influent side of the filter is not essential. Thus, there is no teaching, or suggestion, in Tuompo that the test solution remains on the influent side "for a period of time between 5-minutes to 24-hours" as recited in independent claim 59.

Furthermore, Tuompo teaches that it is explicitly preferred that the chromogenic agent should precipitate on the filter and "rapidly" produce a detectable and intensely colored product. On the contrary, Koumura teaches that the reaction product of the chromogenic agent is dissolved. Furthermore, the incubation times in Koumura are twice that of Tuompo to allow the slow-reacting fluorescent agents to react. Thus, Koumura and Tuompo "teach away" from each other in terms of the "period of time" needed to the substrate to interact with the contaminants. In particular, one of ordinary skill in the would not select a chromogenic agent (i) that is not precipitated on the filter and (ii) that reacts slowly (as taught by

Koumura) for the method taught by Tuompo. Therefore, there is no motivation to make the alleged combination.

For at least these reasons, Tuompo in view of Koumura fail to teach, or suggest, a method of detecting contaminants in a medium suspected of containing such contaminants including (*inter alia*) "allowing the substrate to interact with the contaminants on the influent side of the filter in the filter device for a period of time between 5-minutes to 24-hours, which is sufficient to allow the detectable moiety to be detected in the liquid vehicle" as recited in independent claim 59.

Accordingly, independent claim 59, and claim 60 at least by virtue of its dependency on independent claim 59, are patentable over the cited art.

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CONCLUSION

Accordingly, in view of the above, reconsideration of the objection and rejections and allowance of each of claims 1-13, 15-18, 20-30, 34, 37-42, 44, 45 and 48-60 in connection with the present application is earnestly solicited.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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